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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,860	09/30/2003	Yoshimi Kikuchi	US-111	1661

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,860

Applicant(s)

KIKUCHI ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/8/04, 1/13/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-12 are pending in the case

Election/Restrictions

Applicant's election of SEQ ID NO:3, in the reply filed on 9/24/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5, 6, 9 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/24/04.

Applicant should amend the claims to recite the elected invention, i.e. the method for producing a heterologous protein, comprising culturing a mutant coryneform bacterium having a genetic expression construct wherein a nucleic acid sequence encoding the signal peptide whose sequence is shown in SEQ ID NO:3 is downstream of a promoter sequence which functions in a coryneform bacterium and a nucleic acid sequence encoding a heterologous protein is downstream of said nucleic acid sequence encoding said signal peptide whose sequence is shown in SEQ ID NO:3.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1636

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 8, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 1 is drawn to a method of producing a heterologous protein comprising culturing a mutant coryneform bacterium having a genetic expression construct wherein a nucleic acid encoding a signal peptide region derived from a coryneform bacterium is downstream of a promoter sequence which functions in a coryneform bacterium and a nucleic acid sequence encoding heterologous protein is downstream of said nucleic acid sequence encoding said signal peptide region, said mutant coryneform bacterium have a capacity of secreting the heterologous protein at least 2-fold higher than the wild type *Corynebacterium glutamicum* ATCC 13869. Dependent claim 2 recites that the mutant coryneform bacterium is *C. glutamicum* AJ120036 or a mutant thereof. Dependent claim 3 recites that the mutant coryneform bacterium does not produce a surface protein and is derived from *C. glutamicum* AJ12036. Dependent claim 4 recites that the signal peptide comprises a signal peptide of a cell surface protein from a coryneform

Art Unit: 1636

bacterium, and claim 7 recites that the signal peptide is a from a cell surface protein derived from *C. ammoniagenes*. Dependent claims 10 and 11 recite culture conditions. The specification discloses that the mutant strains encompassed by the claimed invention include any strains obtained by mutagenesis and selection procedures for increased secretory properties (page 10 of the specification). The specification further discloses that such mutants may include those having modifications such that they do not produce surface proteins (page 10 of the specification). The specification further discloses that the signal peptide of any surface protein of Coryneform bacteria is encompassed by the signal peptide recited in the claims.

Claims 1-4, 7, 8, 10 and 11 are genus claims in terms of (1) a method using any mutant coryneform bacteria which secretes a heterologous protein at levels 2-fold higher when compared to wild type *C. glutamicum* ATCC13869 (claims 1, 4, 7, 8, 10, 11) (2) a method using any mutant of AJ12036 which secretes a heterologous protein at levels 2-fold higher when compared to wild type *C. glutamicum* ATCC13869 (claim 2); (3) a method using any mutant coryneform which does not produce a cell surface protein and which is derived from *C. glutamicum* AJ12036 (claim 3). Thus, the claims encompass a broad class of methods using mutant strains of coryneform bacterium, having increased secretory properties.

The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the methods utilizing the encompassed mutant coryneform bacteria, based on the teachings of the specification. While the specification provides broad

Art Unit: 1636

guidance on methods of mutagenesis and selection which may be used to isolate mutant bacteria, there is no disclosure of the precise mutations of coryneform bacteria useful for obtaining the recited increased secretion properties. There is no structure-function analysis on the disclosed strain of *C. glutamicum* AJ12036, or characterization of the mutation(s) contained therein, which result in the desired properties. It cannot be determined what mutations would need to be present to result in the claimed increased secretion properties. The recitation in the claims and specification of methods utilizing mutant bacterial strains which are waiting to be discovered, does not satisfy the written description requirement.

Therefore, the specification does not describe the claimed method utilizing mutant coryneform bacteria having increased secretory properties in such full, clear, concise and exact terms so as to indicate that applicant had possession of the invention recited in the claims at the time of filing the present application.

Vas-Cath V. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of methods utilizing mutant coryneform bacteria, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or

Art Unit: 1636

simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Col. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the disclosed methods using the strain AJ12036, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 7, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 7, and by dependence, claims 2, 4, 8, 10 and 11, are vague and indefinite in the recitation of "derived from". "Derived" is a term that is non-specific and

Art Unit: 1636

relative in nature for which Applicant provides no definition. It provides no clarity as to what Applicant's claimed invention includes and what it does not include. Without a more specific definition, it is impossible to determine what and how many derivations comprise the invention. The nature and number of the derivations to arrive at the invention Applicant seeks to protect with the patent are not established such that a person skilled in the art would be apprised of the metes and bounds of the claims. The limits of the inventions cannot be discerned and others could not know if they were infringing Applicant's claim.

Conclusion

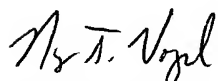
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nancy Vogel, Ph.D.
Patent Examiner